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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,829	10/20/2004	Motoo Sumida	47233-0045	8556

55694 7590 11/09/2007  
DRINKER BIDDLE & REATH (DC)  
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WASHINGTON, DC 20005-1209

EXAMINER
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CUTLIFF, YATE KAI RENE

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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11/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/511,829	Applicant(s) SUMIDA ET AL.	
	Examiner Yate' K. Cutliff	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-32 is/are pending in the application.
- 4a) Of the above claim(s) 8-14, 19, 20 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 15-18, 21-27 and 29-32 is/are rejected.
- 7) ☒ Claim(s) 3 - 5, 7 & 23 - 25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/20/2004, 7/15/2005, 1/30/2006, & 9/13/2007 .

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

The following references were not provided and therefore not considered.

### **FOREIGN PATENTS**

1. Japanese Patent Application No. 11-290094 A, published October 26, 1999.
2. Japanese Patent Application No. 1-202261 A, published August 15, 1989.
3. Japanese Patent Application No. 7-300421 A, published November 14, 1995.

### NON-PATENT DOCUMENTS

VINCENT et al., "Variation de la composition en acides gras des monoesters de zeaxanthine et d' astaxanthine dans rovere et l'hepatopancresa de *Panaeus schmitti* au cours de l'ovogenese," Archives Internationales de Physiologie et de Biochimie, 1989, pp. 71-78, vol. 97, no. 1.

### ***Drawings***

2. The drawings are objected to because figure 1 is not reproducible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

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applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 3, 4, 7, 23 - 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 3 of both claims 3 and 4 it is unclear which medium-chain fatty acid is being referred to, since claim 2 refers to several medium-chain fatty acids.

In line 2 of claim 7, the conjunction between "monoester, astaxanthin" is missing.

Claims 23 – 25 recites the limitation "the medium-chain fatty acid". There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 – 5, 7, 18, 21 – 26, 27 and 32 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Breivik et al. (U.S. 6,709,688).

Applicant claims an astaxanthin medium-chain fatty acid ester that can be a monoester or diester and can have a fatty acid with 8 to 12 carbon atoms, and a composition thereof. Applicant claims an astaxanthin octanoic acid monoester and diester and a composition thereof.

Breivik et al. discloses astaxanthin diester with a C10:0 fatty acid, and references to preparing other diesters with short chain carboxylic acids with chain length C1-C12. (see column 3, lines 5-7, Example 1 and column 8, lines 48 - 56). Breivik et al. discloses a pigment for feed that includes the astaxanthin diester with a C10 fatty acid.

Applicant is reminded that claims 1 and 21 are claimed in a Product-by-Process format.

During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." In re Hyatt, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. Sunrace Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003).

The term "medium-chain" as applied to the astaxanthin medium-chain fatty acid ester has been interpreted to denote "caprylic (octanoic acid), capric (decanoic acid) and lauric (dodecanoic acid)" and/or shorter chain fatty acids as set forth in Applicant's specification at page 3, lines 23 -28 and Kamata et al. (Com. Biochem. Physiol. Vol.

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86B, No., 3. pp 590). Therefore, any astaxanthin medium-chain fatty acid ester is encompassed by the claims.

The PTO takes the following position with respect to Product-by-Process claims.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). "The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. In re Fessmann, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and



the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 7 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breivik et al. (U.S. 6,709,688) and Kamata et al. ((Com. Biochem. Physiol., 1987, Vol. 86B, No., 3. pp 590).

Applicant claims astaxanthin octanoic acid monoester and octanoic acid diester.

The prior art of Breivik et al. substantially discloses the claimed invention as set out above in the 102(b) rejection. The instant claims differ in that Breivik et al. lacks a specific reference to the astaxanthin ester being a octanoic acid monoester and diester; and specific reference to a astaxanthin monoester. However, Breivik et al. shows diesters of astaxanthin were prepared with decanoic acid (a short chain fatty acid) and

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states that other shorter chain carboxylic acids, such as C1-C12 are suitable. (see description in 102(b)). Further, Kamata et al. states that astaxanthin diester contained shorter chain fatty acids. The descriptions of Breivik et al and Kamata et al. are broader than the instant claim. However, based on the disclosure of Breivik et al. it is shown that octanoic acid is a short chain fatty acid, and Kamata et al. makes the inference by noting the presence of C10:0 fatty acid and shorter chains fatty acids. Further, since it is known that an astaxanthin octanoic acid diester exists, it is in the purview of an ordinary artisan that an astaxanthin octanoic acid monoester existed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have both a astaxanthin octaonic acid monoester and octanoic acid diester, as suggested by Breivik et al. and Kamata et al.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claims 21 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breivik et al. (U.S. 6,709,688) and Kamata et al. ((Com. Biochem. Physiol., 1987, Vol. 86B, No., 3. pp 590) in view of Hirschberg et al. (U.S. 5,965,795).

Applicant claims a composition with an astaxanthin medium-chain fatty acid ester that can be a monoester or diester.

Breivik et al. and Kamata et al. substantially disclosed the claimed invention. See 102 (b) rejection. Breivik et al. and Kamta et al. do not explicitly disclose use of an astaxanthin medium-chain fatty acid ester composition in food, food additive and

cosmetic. Hirschberg et al. discloses that it is well known to use an astaxanthin compound in food, cosmetics and food additive. (see column 14, lines 42-52).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce a food, food additive or cosmetic with an astaxanthin as suggested by Hirschberg et al. and have the ester be a astaxanthin medium-chain fatty acid ester as suggested by Breivik et al. and Kamata et al.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. Claims 27 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breivik et al. (U.S. 6,709,688) and Kamata et al. ((Com. Biochem. Physiol., 1987, Vol. 86B, No., 3. pp 590) in view of Hirschberg et al. (U.S. 5,965,795).

Applicant claims a composition with at least one an astaxanthin octanoic acid monoester or astaxanthin octanoic acid diester.

Breivik et al. and Kamata et al. substantially disclosed the claimed invention. See 102 (b) rejection. Breivik et al. and Kamta et al. do not explicitly disclose use at least one an astaxanthin octanoic acid monoester or astaxanthin octanoic acid diester composition in food, food additive and cosmetic. Hirschberg et al. discloses that it is well known to use an astaxanthin compound in food, cosmetics and food additive. (see column 14, lines 42-52).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce a food, food additive or cosmetic with an

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astaxanthin as suggested by Hirschberg et al. and have the ester be a astaxanthin octanoic acid monoester or astaxanthin octanoic acid diester medium-chain fatty acid ester as suggested by Breivik et al. and Kamata et al.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### **Conclusion**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yate' K. Cutliff whose telephone number is (571) 272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272 - 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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